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Overall Healthcare Market and Financing

Hungary's healthcare system is governed by the Ministry of Health and administered by the National Health Insurance Fund (OEP). Although compulsory payroll contributions from both employers and employees are intended to make the OEP financially self-sustaining, it has operated at a deficit since its establishment in 1992.

Hungary spends six to seven percent of its GDP on healthcare. In 1999, this amounted to a per capita health expenditure of approximately USD 300. Pharmaceutical costs are a significant part of healthcare expenditures accounting for 1.3-1.4 % of the GDP (or 25-30% of the country's health care budget).

Utilization of health services in Hungary is fairly high. On average, a person in Hungary visits a physician fifteen times a year (compared to seven visits in Western Europe and North America). The country has an aging population. Nearly 20% of the population is over 60 years of age and the population (10 million) has been decreasing for the last ten years. In 1999, life expectancy for males was 66.5 years and 75 years for females. According to the World Health Organization, Hungary's death rate due to cardiovascular diseases is nearly the highest in the world.

Pharmaceutical Market Dynamics

In 1999, Hungary's pharmaceutical expenditures amounted to approximately HUF 200 billion (nearly USD 800 million). Retail pharmacies registered over 80% of total sales (HUF 165-170 billion). In-patient care institutions used the remaining 15-20%.

There are more than 5,000 drugs registered in Hungary. Of these, approximately 3,000 are over-the-counter (OTC) medications and receive no state subsidies. The remaining 2,000+ drugs are prescription medications and are at least partially state-subsidized. The OTC Pharmaceutical Association estimates that in 1999 only 20-23% of Hungarian drug consumption was OTC. This figure compares to 30-40% in other developed countries. The OTC market share has significantly increased in recent years and this trend is expected to continue.

Before the market was liberalized in 1990, foreign companies had no more than 20% of the pharmaceutical market in terms of value. In 1999, imported drugs accounted for 70% of total pharmaceutical sales (in terms of value) and 30% of total consumption. The average producer price of a packet of Hungarian medicine is about \$1.30 compared to \$5.30 for imported medicine. The average wholesale margin is 8%, while retail margin is 18%. Currently, imported drugs are assessed neither an import duty nor value added tax (VAT) in Hungary. (The VAT is 25%.) However, due to EU accession requirements, this may change in the future.

Generic pharmaceuticals make up 55-60% of all Hungarian-made pharmaceutical products sold in Hungary. Around forty percent of all pharmaceuticals made in Hungary are made under a license and only eight to ten percent are original Hungarian products (although most of these are no longer covered by patents). Hungarian versions of patented medicines accounted for ten percent of all production.

All major Hungarian pharmaceutical companies have been privatized during the last few years. Gedeon Richter Ltd., the largest pharmaceutical company in Hungary, was privatized through a public offering and its shares are currently traded on the Budapest Stock Exchange. ICN Hungary (formerly Alkaloida) is majority-owned by the U.S. pharmaceutical manufacturer ICN, Inc. Pharmavit, a generic and vitamin manufacturer, was acquired by Bristol-Myers-Squibb in 1996. Foreign drug manufacturers have also acquired majority stakes in Chinoin, EGIS, Biogal, and Human. The drug wholesalers and retail pharmacies have also been privatized in recent years. Currently over 50 companies have wholesale licenses, however less than eight have significant turnover.

Hungarian pharmaceutical companies have major export markets in both developed countries and in the former socialist countries, the largest being Russia. About one-third of the Hungarian drug production is being exported.

Reimbursement/Pricing

Hungary has a drug reimbursement system that is administered by the National Health Insurance Fund (OEP) and controlled by the Ministry of Health. Based on the Ministry's proposal, the Parliament approves drug-subsidies as part of the health care budget for the following year. The Ministry continuously revises this subsidy

system and major changes are expected. However, under the present system, the state subsidizes pharmaceutical purchases in one of two ways. By one method, consumers receive reimbursement of a percentage of the drug's retail price (50, 70, 90 or 100%). By the other method, the retail price of the drug already reflects a fixed-amount subsidy based on its active ingredients. "Fixed-amount subsidies" based on active ingredients will become more common under current reform policies. Total subsidies have been approximately equally divided between Hungarian-made and imported pharmaceuticals.

In recent years the National Health Insurance Fund (OEP) has covered 70-75% of Hungary's drug expenses and patients the remaining 25-30%. Each year, the OEP (as the primary drug purchaser in Hungary) and pharmaceutical firms have negotiated the price of more than 2,000 prescription drugs. However, in 1999, the government declined to participate in the negotiations and placed a cap on drug spending. This year the OEP is to switch to funding only "evidence-based medicines", checking the efficacy of the 400 drugs on which it spends 90% of state-subsidies.

Along with the country's total healthcare budget, the drug budget has been decreasing in real terms. Still, drug pricing is a hot political issue in Hungary. Hungarian citizens became accustomed to inexpensive drugs during four decades of the communist era and most still feel entitled to low cost drugs as well as free medical services.

Registration

The National Institute of Pharmacy (OGYI) processes drug registrations in Hungary. There are over 5,000 drugs registered in Hungary of which 550 new products were registered in the last year. Registration fees vary between USD 1,200-4,000 depending on various factors. Drug registration may take up to two years. However, Hungary recognizes the EU centralized procedure (i.e. drugs with EU registration are licensed by the Hungarian Drug Institute within 3 months after all required documents were presented).

A new Drug Law was passed by Parliament in 1998 and came into force at the beginning of 1999. The Law includes the following issues: rules and regulations of drug manufacturing; registration of new pharmaceuticals; clinical trial; packaging-labeling, etc. Most of the rules do not bring around changes, but according to EU rules, these issues have to be regulated by a Law, while Hungary had relevant decrees. As the CEO of the Drug Institute stated, the new international registration process does not mean changes to the old procedures.

There are, however, a few new features. According to EU regulations, non-prescription medicinal products have to be reclassified for distribution as pharmaceuticals, nutritional supplements or cosmetics. Distribution of pharmaceutical products will be limited to pharmacies, groceries and healthfood stores will not sell them.

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